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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,583	12/21/2001	Subraman Rao Cherukuri	24734	2492
7590			EXAMINER	
11/16/2005			COE, SUSAN D	
Subraman Rao Cherukuri			ART UNIT	
6900 English Murfin Way # A			PAPER NUMBER	
Frederick, MD 21703			1655	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,583

Applicant(s)

CHERUKURI ET AL.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2005 has been entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 38 and 39 have been cancelled.
3. Claims 1 and 3-15 are pending.
4. In the paper dated January 29, 2003, applicant elected with traverse hydrogenated starch hydrolysate and lactitol for species A, partially hydrogenated soybean oil for species B, lecithin for species C, dietary fibers for species D, carrageenan for species E, hydroxypropylmethyl cellulose for species F, and psyllium for species G.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 3-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended claim 1 to recite that the composition is non-aerated and the active agents are not coated. Negative limitations are discussed in MPEP section 2173.05(i) which states:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion.

Coatings and aeration are not discussed as embodiments for applicant's invention. The specification discusses aeration in regards to the prior art but is silent on aeration in regards to the claimed composition. Coating of active agents is not discussed. Thus, these negative limitations are not considered to be supported by the disclosure as originally filed. Therefore, these limitations add new matter to the application.

Claim Rejections - 35 USC § 102

6. Claims 1, 3-7, and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,342,631 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the stated claims because the reference does not teach a "soft-chew tablet." However, applicant's specification defines "soft-chew" as "items that are not liquid or gas at room temperature (see page 9, lines 25-29)." A chewing gum certainly meets this definition. In addition, applicant

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teaches that the gum can be in any acceptable form. This is considered to encompass a tablet-type shape. For example, the reference specifically discloses bubble gums which are typically in a tablet type shape.

Claim Rejections - 35 USC § 103

7. Claims 1 and 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,342,631 in view of US Pat. No. 4,824,681.

As discussed above, US '631 is considered to anticipate the claimed soft-chew tablet. The reference specifically discloses using hydrogenated starch hydrolysate, lactitol, hydrogenated vegetable oils, and lecithin (see claims and examples). The reference does not specifically teach using soybean oil, carrageenan, hydroxypropylmethyl cellulose, or psyllium in the composition. US '681 teaches that these ingredients are known to be used in chewing gums to improve various properties of the gums such as the granulation of sweetening agents like lactitol (see column 6 and claim 18). Thus, a person of ordinary skill in the art would reasonably expect that these ingredients could be added to the chewing gum of US '631 in order to best achieve the gum taught by US '631. Based on this reasonable expectation of success, the artisan of ordinary skill would be motivated to make such a modification.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



11-7-05

Susan D. Coe
Primary Examiner
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